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| 09/817,781      | 03/26/2001  | Paul C. Harris       | 2065.2001-000       | 7810             |

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HAMILTON, BROOK, SMITH & REYNOLDS, P.C.  
530 VIRGINIA ROAD  
P.O. BOX 9133  
CONCORD, MA 01742-9133

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| EXAMINER |
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NGUYEN, BAO THUY L 18

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| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 03/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/817,781

Applicant(s)

HARRIS ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's amendment filed December 24, 2002 has been received. Claims 1-32 are pending.
2. Claims 16-32 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.
3. This application contains claims drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
4. The text of those US codes not found in this office action may be found in a previous office action.
5. All rejections not reiterated herein below are withdrawn.

### *Claim Rejections - 35 USC § 112*

6. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-15 are vague and indefinite with respect to the recitation of the analyte-binding particles in part c) of claim 1. These particles are recited as being immobilized in the contact region. However, part d) of claim 1 requires that these particles migrate by capillary action through the sample capture zone, the control capture zone and beyond, into a wicking pad. If these particles are immobilized, how do they move out of the contact region and beyond?

Part e) of claim 1 is also indefinite with respect to the recitation of the binding relationship between the control capture reagent and the analyte-binding particles. What exactly does the control capture reagent bind to? The analyte that is bound by the analyte-binding agent on the particles? Or the analyte-binding agent itself? Or the particles? Does the control capture reagent bind to the analyte-binding particle irrespective of the presence or absence of analyte? In other words, does it bind excess analyte-binding particle, i.e. those that do not have analyte bound to them?

Part h) is indefinite because it is unclear how the exactly, the amount of analyte is corrected. It is also unclear how the amount of variability in the reaction of the analyte-binding particles with the surfaces of the assay is compensated.

### *Response to Arguments*

7. Applicant's arguments filed December 24, 2002 have been fully considered but they are not persuasive.

Applicant argues that the specification and the claims clearly teaches that the particles moves with the sample fluid and that "immobilized" refers to particles that are coated on and/or permeated in the membrane.

These arguments have been fully considered but are not persuasive. It is noted that although the claims are interpreted in light of the specification, limitations in the specification are not read into the claims. In addition, while a term used in the claims may be given a special meaning in the description of the invention, generally no term may be given a meaning repugnant to the usual meaning of the term. In *re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). "Immobilized" is accepted in the prior art as "firmly in position, or not mobile", therefore, until

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the meaning of a term or phrase used in a claim is clear, a rejection under 35 U.S.C. 112, second paragraph is appropriate. Furthermore, the claim contradicts itself when reciting that the particles are immobilized, yet can be mobilize and move by capillary action through the test strip.

It suggested that Applicant change “immobilized” to –coated – to obviate the rejection.

Applicant argues that the specification teaches that the “contacted analyte-binding particles” may or may not have analyte bound to the analyte-binding agent. This argument has been fully considered but is not deemed to be persuasive. Again, it is noted that although the claims are interpreted in light of the specification, limitations in the specification are not read into the claims. The claim has been rejected as being indefinite because it is unclear what exactly does the control capture reagent bind to. The argument submitted further demonstrates the fact that the claim is indefinite because the control reagent can bind to the analyte-binding particles regardless of the presence or absence of analyte. Since the preamble recites a method for quantitatively measuring the amount of analyte in a sample, it is necessary that any amount of analyte capture in both the sample capture zone and the control zone be determine, therefore, it must be clear whether the control reagent captures any analyte.

Applicant argues that the amount of corrected analyte binding particles can be determined using the description in the specification. Applicant argues that the behavior of the analyte-binding particles with regard to the control capture reagent is used to compensate for the amount of variability in the reaction of the analyte-binding particles with the surfaces of the assay and the amount of the variability of the analyte binding particles can be taken into consideration in a determination of the amount of the analyte of interest. Applicant further argues that step (h) has been amended to indicate that the corrected analyte-binding particles

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amount is determined by compensating for the amount of the variability in the reaction of the analyte binding particles with the surfaces of the assay.

These arguments have been fully considered but are not deemed to be persuasive. Once more, it is noted that although the claims are interpreted in light of the specification, limitations in the specification are not read into the claims. With exception to the specific citation regarding determination of the analyte-binding particles by taking a ratio of between the amount of analyte binding particles in the sample capture zone, and the amount of analyte binding particles in the control capture zone; or a ratio between the amount of analyte binding particles in the sample capture zone and the sum of the amount of analyte-binding particles in the control zone and zone and the sample capture zone, all other arguments are not persuasive. It appears that Applicant's argument further reinforce the fact that the claim is indefinite and confusing. What exactly does it mean to "compensate for the amount of the variability in the reaction of the particles with the surfaces of the assay using the behavior between the particles and the control reagent?" What does the surface of the assay has to do with how much analyte is in a sample? The arguments do not address the problem, i.e. step (h) is confusing. It is suggested that applicant include, in step (h), the determination of the analyte by using the various ratios recited in claims 2 and 3.

*Claim Rejections - 35 USC § 102*

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuo et al (US 6,436,721 B1) for reasons of record in paper no. 8.

*Response to Arguments*

10. Applicant's arguments filed December 24, 2002 have been fully considered but they are not persuasive.

Applicant argues that Kuo teaches an immobilized binding partner in the sample capture zone that binds to an epitope of the analyte that is different from the epitope to which the labeled binding partner is specific. And that the instant invention contemplates that the sample capture reagent can be directed against the same epitope of the analyte.

This argument has been fully considered but is not deemed persuasive. The instant claims are not limited only to capture binding agent directed against the same epitope of the analyte. Instead the claims encompass capture binding agents direct<sup>ed</sup> against different epitope of the analytes as well. In which case, Kuo anticipates the claims.

Applicant argues that Kuo teaches a second zone containing immobilized analyte, such a zone is not present in the instant claims. Applicant also argues that Kuo teaches a fourth zone

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used in a ratio to correct for the concentration of the analyte, such a zone is not required in the instant claims.

These arguments have been fully considered but are not persuasive. It must be noted that Kuo discloses the invention as claimed. The fact that it discloses additional structure not claimed is irrelevant.

Applicant argues that because the ratio of the signals taught by Kuo measure<sup>s</sup> antigen concentration, they do not compensate for assay variability in the reaction of analyte binding particles with the surfaces of the membrane strip as claimed. This argument has been fully considered but is not deemed to be persuasive. Kuo teaches the same method for determining the concentration of analyte, i.e. by taking a ratio of the measured signal in the sample capture zone and the control capture zone, therefore, Kuo anticipates the claims. The arguments that the claims call for compensating the amount of variability in the reaction with the surface of the membrane strip have been considered but are not persuasive. It is unclear how this compensation is done. There is nothing in the claims or the specification about compensating for the variability other than the ratios measurement, which is taught by Kuo.

### *Conclusion*

**11.** No claim is allowed.

**12. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until




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after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**13.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641  
March 4, 2003